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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/822, 186 03/20/97 RUEGER

D CRP-137

 EXAMINER

HM12/0412

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ART UNIT

PAPER NUMBER

*18*1646  
DATE MAILED:

04/12/99

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>08/822,186</b>	Applicant(s) <b>Rueger et al.</b>
	Examiner <b>David S. Romeo</b>	Group Art Unit <b>1646</b>

Responsive to communication(s) filed on 1-27-99

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-33, 35, and 36 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-33, 35, and 36 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-25, 31-33, 35 and 36, drawn to a composition comprising an osteogenic protein, classified in class 530, subclass 350.
  - II. Claims 26-30, drawn to a method of inducing bone or cartilage formation, classified in class 514, subclass 12.
2. The inventions are distinct, each from the other because of the following reasons:  
Inventions I and II are related as product and process of use. The inventions can be shown to be  
10 distinct if either or both of the following can be shown: (1) the process for using the product as  
claimed can be practiced with another materially different product or (2) the product as claimed  
can be used in a materially different process of using that product (MPEP § 806.05(h)). In the  
instant case the product as claimed can be used in a materially different process of inducing the  
formation of dentine.  
~
- 15 3. Because these inventions are distinct for the reasons given above, have acquired a separate  
status in the art as shown by their different classification, require separate searches and have

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acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Claims 1-4, 6-16, 20-30, 32, 33, 35 and 36 are generic to a plurality of disclosed patentably distinct species of osteogenic proteins comprising the species disclosed at page 28, full paragraph 2, through page 29, full paragraph 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Claims 1-12, 14-16, 18-30, 32, 33, 35 and 36 are generic to a plurality of disclosed patentably distinct species of binding agents comprising the species disclosed at page 42, full paragraph 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Claims 1-16, 18-30, 32, 33, 35 and 36 are generic to a plurality of disclosed patentably 5 distinct species of matrix comprising the species disclosed at the paragraph bridging pages 17-18.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to 10 be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Claims 1-26, 29-33, 35 and 36 are generic to a plurality of disclosed patentably distinct species comprising bone formation and cartilage formation. Applicant is required under 35 15 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Claims 1-33, 35, and 36 are generic to a plurality of disclosed patentably distinct species  
5 of defect site comprising the species at page 15, line 1, through page 17, line 2, and/or in claim  
29. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though  
this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct,  
applicant should submit evidence or identify such evidence now of record showing the species to  
10 be obvious variants or clearly admit on the record that this is the case. In either instance, if the  
examiner finds one of the inventions unpatentable over the prior art, the evidence or admission  
may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is advised that the reply to this requirement to be complete must include an  
election of the invention to be examined even though the requirement be traversed (37  
15 CFR 1.143).

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10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the  
5 fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday from 6:45 a.m. to 3:15 p.m.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4242.

Faxed draft or informal communications should be directed to the examiner at (703) 308-0294.

10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*David S. Romeo*  
**DAVID ROMEO**  
**PATENT EXAMINER**

April 10, 1999